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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/775,953

02/09/2004

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EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

11/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/775,953	Applicant(s) BROCIA, ROBERT W.	
	Examiner Ralph Gitomer	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The amendment received 9/15/08 has been entered and claims 1, 13, 15 are currently pending in this application. In view of the arguments presented and amendments to the claims, the rejection of record under 35 USC 112, second paragraph, is hereby withdrawn.

Although not claimed, the point of novelty may be directed to assaying enzyme activity by reacting the enzyme with a substrate, thus producing hydrogen peroxide as a product, and the peroxide then collisionally quenches a selected fluorophore, determining the amount of quenching of the fluorophore and correlating the amount of quenching to the enzyme activity.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Morris in view of Lakowicz.

Morris (5,173,434) entitled "Measurement of Color Reactions by Monitoring a Change of Fluorescence" teaches in column 2 last paragraph, fluorescence quenching is described for fluorogenic substrates for assaying enzymes. The synthetic substrate contains a quenching and fluorescing group which is generated. In column 4 line 24 the assay detects the concentration of substances in a colorimetric, turbidimetric or

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nephelometric reaction with a reader. In column 5 first full paragraph, chromogenic reagents are disclosed which have an absorption spectrum that overlaps the spectrum of a fluorophore. See the claims.

The claims as amended differ from Morris in that the analyte determined physically interacts with the fluorophore to prevent light emission from the fluorophore by collisional quenching whereas Morris absorbs light emitted from the fluorophore by absorbance quenching.

Lakowicz (Principles of Fluorescence Spectroscopy) teaches on page 257 second paragraph, both static and dynamic quenching require molecular contact between the fluorophore and quencher. In the case of collisional quenching, the quencher must diffuse to the fluorophore during the lifetime of the excited state. Upon contact, the fluorophore returns to the ground state, without emission of a photon. In the case of static quenching a complex is formed between the fluorophore and the quencher, and this complex is nonfluorescent. In either event, the fluorophore and quencher must be in contact. On page 258 last full paragraph, fortunately a wide variety of substances act as quenchers of fluorescence. One of the best known collisional quenchers is molecular oxygen, which quenches almost all known fluorophores. On page 258 last line bridging to page 259, other collisional quenchers include hydrogen peroxide. On page 258 last paragraph, because a variety of substances act as quenchers, one can frequently identify fluorophore-quencher combinations for a desired purpose. It is important to note that not all fluorophores are quenched by all the substances listed above. This fact occasionally allows selective

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quenching of a given fluorophore. The occurrence of quenching depends upon the mechanism, which in turn depends upon the structures of the individual molecules. On page 265 last paragraph dynamic and static quenching are discussed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the collisional quenching of Lakowicz in the method of Morris because Morris employs absorbance quenching which is selective to some degree and Lakowicz employs collisional quenching for the same function of the absorbance quenching of Morris but likely achieves greater sensitivity and specificity because collisional quenching is more specific regarding the compound that quenches and has a greater quenching effect than absorbance as related to concentration.

Applicant's arguments filed 9/15/08 have been fully considered but they are not persuasive.

Applicants response argues that Morris measures enzyme activity, not the concentration of a substrate for an enzyme. And the fluorescent matrix of Morris does not provide collisional quenching

It is the examiner's position that Morris teaches in column 2 determining the product of enzymatic reactions where the fluorescent substrates of enzymes are determined. Lakowicz was cited to teach collisional quenching and its mechanism of action and applications.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

Ralph Gitomer
Primary Examiner
Art Unit 1657